Application Note

Automated high-throughput liquid transfer of SDS samples

Transfer of eluates for protein quantitation using the oPA method

Introduction

Surgical instruments, such as scalpels and forceps, are medical products that are used repeatedly on different patients. Therefore, after every use, these instruments must be thoroughly cleaned using special instrument cleaners, in order to remove residues as well as contaminants and microorganisms. Only after a satisfactory cleaning, can the instruments be disinfected in a chemical, thermal or chemothermal process. In the case of invasive surgical instruments, a sterilization process is then carried out.

Materials and Methods

In the course of assessing these processes, in particular the cleaning performance as it pertains to a validation, quantitative methods for detecting protein residues are implemented to monitor the cleaning success of instruments in the medical field. The DIN EN ISO 15883-1 standard, the KRINKO BfArM recommendation and the guideline compiled by the DGKH, DGSV and AKI for the "Validation and routine monitoring of automatic cleaning and thermal disinfection processes for medical products" (5th edition, 2017) all list the oPA and BCA/Biuret methods as detection methods.

Image 1: Sterilization of invasive surgical instruments in autoclaves

Integrating the liquid handling station into the laboratory process

Valitech GmbH & Co. KG is one of the leading providers of validation services in the field of hygiene and medical product treatment in private medical practices and hospitals. The company's core business is validating treatment processes, and an in-house analysis laboratory is indispensable for this. In addition to the production of test specimens, protein-chemical analysis of samples taken during the validations is one of the primary functions of the laboratory.

One of the challenges of applying the above-mentioned detection method now is the swift processing of samples, which are taken in the course of process validation. Therefore, Valitech initiated the high-throughput analysis of eluates in its own analysis laboratory. In this context, the integration of BRAND's liquid handling station into Valitech's laboratory process helps to automatically transfer SDS (sodium dodecyl sulfate) samples.

Image 2+3: Integrating the liquid handling station into process validation at Valitech GmbH & Co.KG

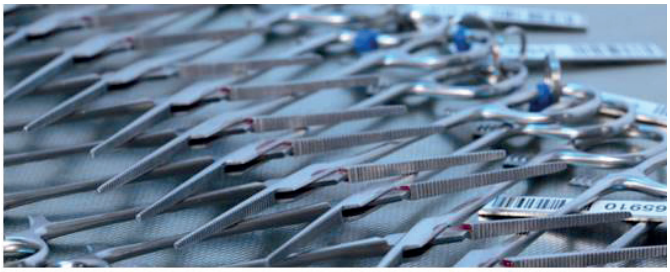

Image 4: Standardized contaminated test specimens (crile clamps) for use during validation.

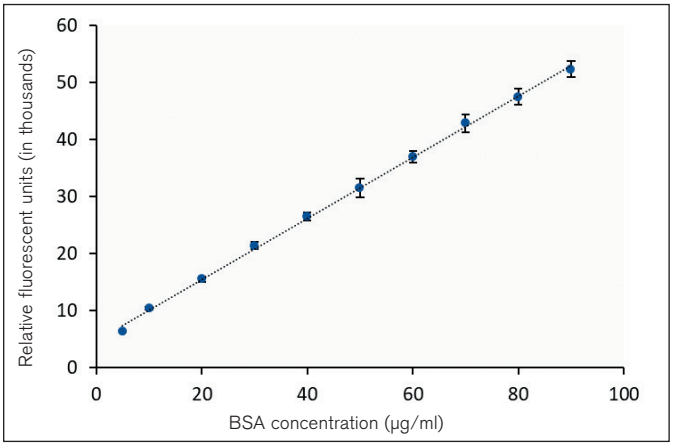

Figure 1: Exemplary depiction of the relative fluorescent units of a BSA (Bovine Serum Albumin) – standard series. Plotted are the mean values, including error indicators of the concentrations of 5-90 µg/ml BSA (N = 7; R^2 = 0.999).

Results

With a sample count of approx. 3,500 eluates per week, which were extracted by Valitech employees during process validations and which also originated from routine in-house medical facility tests, high demands are placed on the laboratory equipment used. Therefore, the liquid handling station being used must be extremely reliable. It is the only way to ensure the continuous and timely processing of the samples. With an average operating time of about 80 hours per month, the error rate of < 1 % fully complies with internal requirements.

The error management feature of the control software can also be used to eliminate extremely rare errors within a short time, with complete documentation.

Another crucial requirement is the precision with which the samples are transferred. Samples are pipetted several times during residual protein analysis to improve reliability of the results. Using the liquid handling station ensures high consistency of the replicates. Figure 1 shows a BSA (Bovine Serum Albumin) standard series used by Valitech, whose concentrations (Table 1) from a stock solution (1mg/ml BSA) were created by the LHS. The LHS also distributed the individual concentrations onto the microtiter plate. The dispersion of the individual replicates of all BSA concentrations used always meets the internal precision requirements. With the help of the intuitive control software, the pipetting programs required for this are also quickly created. The LHS is therefore an integral part of the Valitech's analysis process.

Pipetted BSA volume (µl)	Pipetted SDS volume (µl)	Target concentration BSA (µl/ml)	$\bar{X}$ Rel. fluorescent units	± σ Rel. fluorescent units
50	950	5	6367	142
100	900	10	10422	271
200	800	20	15540	442
300	700	30	21433	643
400	600	40	26573	727
500	500	50	31566	1686
600	400	60	37027	1058
700	300	70	42874	1620
800	200	80	47543	1399
900	100	90	52376	1454

Table 1: Volumes of BSA and SDS, which were pipetted by the LHS for the standard series. Also shown are the mean values ($\bar{X}$) of the measured fluorescent units as well as the corresponding standard deviation (σ). N = 7.

9941 21 · Printed in Germany · WA/0219